JUN 2 8 2001

510(k) Summary of Safety and Effectiveness ArthroCare Corporation ArthroCare ArthroWands®

K011083

General Information

Manufacturer: ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94085-2936

Establishment Registration Number: 2951580

Contact Person: Bruce Prothro
Vice President, Regulatory Affairs, Quality Assurance, and Clinical Research

Date Prepared: June 11, 2001

Device Description

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Trade Name: ArthroCare ArthroWands®

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

ArthroCare® System 2000	K001588
Linvatec UltrAblator™ Electrode	K993885
Oratec® Vulcan™ Electrosurgical Probes	K000691

Intended Use

The ArthroCare ArthroWands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
Ablation and Debridement	
• ACL/PCL	Knee
• Acromioplasty	Shoulder
• Articular Cartilage	All Joints
• Bursectomy	All Joints
• Chrondroplasty	All Joints

• Facia	All Joints
• Ligament	All Joints
• Notchplasty	Knee
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Subacromial Decompression	Shoulder
• Synovectomy	All Joints
• Tendon	All Joints
Excision and Resection	
• Acetabular Labrum	Hip
• Articular Labrum	All Joints
• Capsule	All Joints
• Capsular Release	Knee
• Cartilage Flaps	Knee
• Cysts	All Joints
• Discoid Meniscus	Knee
• Frozen Shoulder Release	Shoulder
• Glenoidale Labrum	Shoulder
• Lateral Release	Knee
• Ligament	All Joints
• Loose Bodies	All Joints
• Meniscal Cystectomy	Knee
• Meniscectomy	Knee
• Plica Removal	All Joints
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Synovial Membrane	All Joints
• Tendon	All Joints
• Triangular Fibrocartilage (TFCC)	Wrist
• Villusectomy	Knee
Coagulation	
• ACL/PCL	Knee
• Articular Cartilage	All Joints
• Carpal Ligaments	Wrist
• Glenohumeral Capsule	Shoulder
• Ligament	All Joints
• Medial Retinaculum	Knee
• Rotator Cuff	Shoulder
• Tendon	All Joints
• Wrist Tendons	Wrist

Product Description

The ArthroCare ArthroWands are bipolar, high frequency electrosurgical devices designed for arthroscopic and orthopedic procedures.

Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare evaluated the indications for use, materials incorporated, product specifications and energy requirements of those systems. The expansion of the indications to include specific arthroscopic and orthopedic procedures does not raise any new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Bruce Prothro
Vice President, Regulatory Affairs,
Quality Assurance, and Clinical Research
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94085

Re: K011083
Trade/Device Name: ArthroCare ArthroWands®
Regulation Number: 888.1100, 878.4400
Regulatory Class: II
Product Code: HRX, GEI
Dated: April 9, 2001
Received: April 10, 2001

Dear Mr. Prothro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Device Name: ArthroCare ArthroWands®
510(k) Number: K011083

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use ____

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011083